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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-12-0740]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects.

To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404-639-7570 and send comments to Kimberly Lane, CDC Reports Clearance Officer, 1600 Clifton Road, MS-D74, Atlanta, GA 30333 or send an e-mail to omb@cdc.gov.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and

clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

Proposed Project

Medical Monitoring Project (MMP) - (OMB No. 0920-0740 Exp: 5/31/2012) – Revision -- National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

This proposed data collection supplements the HIV/AIDS surveillance programs in 23 selected state and local health departments, which collect information on persons diagnosed with, living with, and dying from HIV infection and AIDS and will incorporate data elements from two data collections: Supplement to HIV/AIDS Surveillance (SHAS) project (0920-0262) and the Adult/Adolescent Spectrum of HIV Disease (ASD). Both projects stopped data collection in 2004. Although CDC receives surveillance data from all U.S. states, these supplemental surveillance data are needed to make population-based national estimates of key indicators, related to the quality of HIV-

related ambulatory care, the severity of need for HIV-related care and services, and HIV-related behaviors and clinical outcomes.

This project collects data on behaviors and clinical outcomes from a probability sample of HIV-infected adults receiving care in the U.S. through in-person or telephone interviews and abstraction of medical records. Information is also extracted from HIV case surveillance records for a dataset, referred to as the minimum dataset, which is used to assess non-response bias, for quality control, to improve the ability of MMP to monitor ongoing care and treatment of HIV-infected persons, and to make inferences from the MMP sample to HIV-infected persons in care nationally. No other Federal agency collects nationally representative population-based behavioral and clinical information from HIV-infected adults in care. The data are expected to have significant implications for policy, program development, and resource allocation at the state/local and national levels.

The Centers for Disease Control and Prevention request approval for a revision and 3-year approval for the previously approved Medical Monitoring Project (MMP) 0920-0740 exp. 5/31/2012). The interview and minimum dataset data collection instruments have

been revised based on experience in previous data collection cycles, but these changes will not affect the burden per respondent. The medical record abstraction forms have not changed. CDC's current goal is to interview 80% of 9,400 patients or 7,520, 96% of whom (a total of 7,219 patients) will complete the standard interview and 4% of whom (a total of 301 patients) will complete the short interview. The number of sampled patients has increased by 62 patients compared to the previously approved information collection; thereby increasing the total burden hours by 37 hours, from 8,500 to 8,537.

Data will be collected through in-person and telephone-administered, computer-assisted interviews conducted by trained interviewers in 23 Reporting Areas (16 states, Puerto Rico and 6 separately funded cities), through medical record and abstraction by trained abstractors and through extraction of information from HIV surveillance case records. The project activities and methods will remain the same as those used in the previously approved data collection period.

Interviews with HIV-infected patients provide information on patient demographics, and the current levels of behaviors that may facilitate HIV transmission: sexual and drug use behaviors; patients' access to, use of and barriers to receiving HIV-

related secondary prevention services; utilization of HIV-related medical services; and adherence to drug regimens.

Collection of data from patient medical records provides information on: demographics and insurance status; the prevalence and incidence of AIDS-defining opportunistic illnesses and co-morbidities related to HIV disease; the receipt of prophylactic and antiretroviral medications; and whether patients are receiving screening and treatment according to Public Health Service guidelines.

The minimum dataset contains demographic and HIV-related laboratory test information extracted from an existing HIV case surveillance database, the national HIV/AIDS Reporting System.

A standard interview will be conducted with approximately 96% of patients, and will take 45 minutes. A short interview will be conducted with patients who are too ill to complete the standard interview or when the interview must be translated. The short interview, which will be conducted with approximately 4% of patients, will take approximately 20 minutes.

Medical record abstractions will be completed on all eligible participants. Minimal data on all sampled patients will be extracted from the national HIV/AIDS Reporting System.

Participation of respondents is voluntary. There is no cost to the respondents other than their time.

Estimated Annualized Burden Hours

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Burden (in hours)
Sampled, Eligible HIV-Infected Patients	Standard interview	7219	1	45/60	5,414
Sampled, Eligible HIV-Infected Patients Unable to Complete the Standard Interview	Short interview	301	1	20/60	100
Facility office staff pulling medical records		7,520	1	3/60	376
Facility office staff providing Estimated Patient Loads		936	1	2	1,872
Facility office staff providing patient lists		1,030	1	30/60	515
Facility office staff approaching participants for enrollment		3,120	1	5/60	260
Total					8,537

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